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<p>(54) Title: ENDOCARDIAL LEAD SYSTEM</p> <p>(57) Abstract</p> <p>An endocardial lead (20) comprising an elongate body having a first defibrillation coil electrode (40), a second defibrillation coil electrode (44) and a first pacing/sensing electrode (42). The first defibrillation coil electrode has a first end at or near the distal end of the elongate body and a second end spaced longitudinally from the distal end. The first pacing/sensing electrode (42) is spaced longitudinally along the peripheral surface from the second end of the first defibrillation coil electrode and is disposed at a curved portion of the lead body. The second defibrillation coil electrode is spaced longitudinally along the peripheral surface from the first pacing/sensing electrode to afford positioning the first defibrillation coil longitudinally adjacent an apical location of the right ventricle (50) of a heart with the first pacing/sensing electrode within the right ventricle and the second defibrillation coil (44) within the right atrial chamber (52) or a major vein (54) leading to the right atrial chamber.</p>		

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ENDOCARDIAL LEAD SYSTEM

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Technical Field

The present invention relates generally to medical devices and in particular to implantable endocardial catheters for use with medical devices.

Background of the Invention

Ventricular fibrillation of the heart is characterized by fine, rapid,
10 fibrillatory movements of the ventricular muscle that replace the normal cardiac contraction. Since very little pumping action occurs during ventricular fibrillation, the situation is fatal unless quickly corrected by cardiac conversion. During conversion, defibrillation level electrical energy is applied to the heart in an attempt to depolarize the myocardial tissue of the heart and allow a normal
15 sinus rhythm to be reestablished.

One theory that has been proposed to explain the mechanism of conversion by the application of defibrillation electrical current is the critical mass hypothesis. The critical mass hypothesis suggests that it is not necessary to halt all fibrillation activity in order to have defibrillation occur, but that it is
20 sufficient to halt only a "critical mass" (perhaps 75%) of the myocardium in the ventricles. In this theory, the assumption is made that if all fibrillation activity is localized to a region smaller than the critical mass of myocardium, the remaining fibrillation activity is not capable of maintaining fibrillation and will die out after one or two cycles, resulting in normal sinus rhythm.

25 Implantable cardioverter/defibrillators (ICDs) have been successfully used to treat patients who have experienced one or more documented episodes of hemodynamically significant ventricular tachycardia or ventricular fibrillation. The basic ICD consists of a primary battery, electronic circuitry to control both the sensing of the patient's cardiac signals and the
30 delivery of electrical shocks to the patient's heart, and a high-voltage capacitor bank housed within a hermetically sealed titanium case. One or more catheter leads having defibrillation electrodes are implanted within the heart of the patient or on the epicardial surface of the patient's heart. The catheter leads are

then coupled to the implantable housing and the electronic circuitry of the ICD and are used to deliver defibrillation level electrical energy to the heart.

It has been suggested that a minimum and even (*i.e.*, similar in all parts of the ventricles) potential gradient generated by a defibrillation level shock is necessary for effective cardiac defibrillation. This potential gradient is affected, and thus determined, by the voltage of the shock and the electrode configuration employed. It has also been suggested that a maximum potential gradient also exists that, beyond this value, deleterious electrophysiological and mechanical effects may occur, such as new arrhythmias, myocardial necrosis, or contractile dysfunction. Therefore, how and where defibrillation electrodes are placed on and/or within the heart has a major effect on whether or not a critical mass of cardiac tissue is captured during a defibrillation attempt.

Endocardial defibrillation catheters, those not requiring a thoracotomy to be placed on the heart, have a major advantage over the epicardial lead systems by reducing the morbidity, mortality, and cost of thoracotomy procedures. However, a major problem with these systems is the potential for high defibrillation thresholds as compared to system employing epicardial defibrillation electrodes. Changes to the waveform of the defibrillation shock and to the combinations of endocardial leads implanted into a patient and the current pathways used can result in efficacious defibrillation therapy being delivered to the patient.

The easiest and most convenient way to perform the implantation of a fully transvenous system is to use only one endocardial lead with both sensing and pacing and defibrillation capabilities. One such endocardial lead is sold under the trademark ENDOTAK C (Cardiac Pacemaker, Inc./ Guidant Corporation, St. Paul, MN), which is a tripolar, tined, endocardial lead featuring a porous tip electrode (placed in the apex of the right ventricular) that serves as the cathode for intracardiac right ventricular electrogram rate sensing and pacing, and two defibrillation coil electrodes, with the distal one serving as the anode for rate sensing and as the cathode for morphology sensing and defibrillation which the proximal coil electrode positioned within the superior vena cava functions as the anode for defibrillation.

However, single body endocardial leads used for both defibrillation and rate sensing have been reported to suffer technical inadequacies that may pose significant risks to the patient. Endocardial electrograms obtained from integrated sense/pace-defibrillation leads have been shown to be affected after shock delivery, with their amplitude decreasing to such a significant degree that arrhythmia redetection is dangerously compromised. As already mentioned above, obtaining adequate defibrillation thresholds has been a major problem with the nonthoracotomy endocardial lead systems. Therefore, a need exists to design an endocardial lead system that effectively reduces defibrillation thresholds and allow for reliable post-defibrillation shock sensing and pacing.

Summary of the Invention

The present invention provides a single body endocardial lead, and an implantable apparatus for its use, that reduces defibrillation thresholds and improves post-defibrillation shock therapy redetection. One aspect of these improvements is the placement of the electrodes on the endocardial lead. The electrode configuration on the endocardial lead improves the potential gradient generated by a defibrillation level shock, which increases the effectiveness of the cardiac defibrillation shock and reduces the defibrillation threshold as compared to conventional endocardial leads. Also, the position of the pacing electrode relative to the defibrillation electrodes provides for a more reliable and accurate post-defibrillation shock electrogram. Furthermore, the reduction in defibrillation thresholds allows for reduced battery consumption of the implantable device, potentially prolonging the life of the device and/or allowing for an overall reduction in the size of the device.

The endocardial lead of the present invention has an elongate body with a peripheral surface, a proximal end, a distal end, and a first defibrillation coil electrode and a first pacing/sensing electrode on the peripheral surface. The first defibrillation coil electrode is positioned on the endocardial lead at or near the distal end of the elongate body. The first pacing/sensing electrode is spaced longitudinally along the peripheral surface from the first defibrillation coil electrode to afford positioning both the first defibrillation coil and the first pacing/sensing electrode in a right ventricle of a heart. In one

embodiment, the endocardial lead is positioned within the right ventricle of the heart with the first defibrillation coil electrode positioned longitudinally adjacent the right ventricular septal wall. In an additional embodiment, the endocardial lead is positioned within the right ventricle of the heart with the first
5 defibrillation coil electrode positioned directly within the ventricular apex, where the first defibrillation coil is longitudinally adjacent to the apex of the right ventricle of the heart.

In an additional embodiment of the invention, the endocardial lead further includes a second defibrillation coil electrode on the peripheral
10 surface. The second defibrillation coil electrode is spaced longitudinally along the peripheral surface from the first pacing/sensing electrode to afford positioning the first defibrillation coil and the first pacing/sensing electrode within the right ventricle and the second defibrillation coil within the supraventricular region of the heart. In one embodiment, the second
15 defibrillation coil electrode is positioned within a right atrial chamber or a major vein leading to the right atrial chamber of the heart.

Different types and configurations of first pacing/sensing electrodes can be used with the endocardial lead of the present invention. In one embodiment, the first pacing/sensing electrode includes a retaining element
20 integrated into or positioned adjacent the first pacing/sensing electrode. The retaining element is adapted to be embedded in the tissue of the right ventricle of the heart to secure the first pacing/sensing electrode, and the elongate body of the endocardial lead, to the right ventricle of the heart. In one embodiment, the retaining element is a helical wire which used to secure the first pacing/sensing
25 electrode to the cardiac tissue of the ventricular septum.

In an additional embodiment, the peripheral surface of the elongate body defines an electrode housing having an opening, the housing being adapted to sheathe the first pacing/sensing electrode and the retaining element and through which the first pacing/sensing electrode and/or the retaining element
30 extends from the peripheral surface to engage the right ventricular chamber of the heart. A stylet lumen extends through the elongate body of the endocardial lead to the first pacing/sensing electrode and is adapted to receive a stylet that is used for extending and rotating the first pacing/sensing electrode and the

retaining element to embed the retention element of the first pacing/sensing electrode into the right ventricle of the heart.

In an alternative embodiment, the elongate body of the endocardial lead further has a curved portion spaced between the proximal end and the distal end. The curved portion has an outer radial surface and an inner radial surface, where the outer radial surface generally has a larger radius of curvature than the inner radial surface. The electrode housing of the first pacing/sensing electrode is positioned generally on the outer radial surface of the curved portion such that when the first pacing/sensing electrode is extended beyond the peripheral surface of the elongate body to engage the tissues of the heart it is along an axis that is essentially parallel with a longitudinal axis of the proximal end of the elongate body. In one embodiment, the curved portion creates an angle of between approximately 45 to 60 degrees relative to a longitudinal axis of the distal end and a longitudinal axis of the proximal end of the elongate body.

In an alternative embodiment, the curved elongate body has a first pacing/sensing electrode that is a porous woven mesh having a semi-spherical shape located on the peripheral surface of the elongate body. The porous woven mesh semi-spherically shaped first pacing/sensing electrode is generally positioned on the outer radial surface of the curved portion such that when the endocardial lead is implanted in the body, the first defibrillation coil electrode is positioned in the right ventricular apex and the first pacing/sensing electrode is in physical contact with the tissues of the right ventricle chamber of the heart. In one embodiment, the first pacing/sensing electrode is positioned on the septal wall of the right ventricle of the heart.

In an alternative embodiment, the first pacing/sensing electrode is an annular or semi-annular ring electrode, as are known in the art, generally positioned on the outer radial surface of the curved portion such that when the endocardial lead is implanted in the body, the first defibrillation coil electrode is positioned in the right ventricular apex and the first pacing/sensing electrode is in physical contact with the tissues of the right ventricle chamber of the heart.

Brief Description of Drawings

In the drawings, where like numerals describe like components throughout the several views:

Figure 1 is a schematic view of an implantable
5 cardioverter/defibrillator with one embodiment of an endocardial lead implanted in a heart from which segments have been removed to show details;

Figure 2 is a schematic view of one embodiment of an endocardial lead according to the present invention;

Figure 3 is a cross-sectional view of the embodiment of an
10 endocardial lead according to Figure 2 taken along the lines 3-3;

Figure 4 is a schematic view of one embodiment of an endocardial lead according to the present invention;

Figure 5 is a schematic view of an implantable cardioverter/defibrillator with one embodiment of an endocardial lead implanted
15 in a heart from which segments have been removed to show details;

Figure 6 (A-C) are enlarged segmentary views of one embodiment of an electrode housing on an endocardial lead according to the present invention;

Figure 7 is a block diagram of an implantable
20 cardioverter/defibrillator according to the present invention;

Figure 8 is a schematic view of an embodiment of an endocardial lead according to the present invention;

Figure 9 is a schematic view of an embodiment of an endocardial lead according to the present invention;

25 Figure 10 is a schematic view of an embodiment of an endocardial lead according to the present invention;

Figure 11 is a cross-sectional view of the embodiment of an endocardial lead according to Figure 10 taken along the lines 11-11; and

Figure 12 is a schematic view of an implantable
30 cardioverter/defibrillator with one embodiment of an endocardial lead implanted in a heart from which segments have been removed to show details.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof and in which is shown by way of illustration specific embodiments in which the invention may be practiced.

5 These embodiments are described in sufficient detail to enable those skilled in the art to practice and use the invention, and it is to be understood that other embodiments may be utilized and that electrical, logical, and structural changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a
10 limiting sense and the scope of the present invention is defined by the appended claims and their equivalents.

Referring now to Figure 1 of the drawings, there is shown one embodiment of an apparatus 20 including a cardioverter/defibrillator 22 physically and electrically coupled to an endocardial lead 24. The apparatus 20
15 is implanted in a human body 26 with portions of the endocardial lead 24 inserted into a heart 28 to detect and analyze electric cardiac signals produced by the heart 28 and to provide electrical energy to the heart 28 under certain predetermined conditions to treat ventricular arrhythmias, including ventricular tachyarrhythmias and ventricular fibrillation, of the heart 28.

20 The endocardial lead 24 comprises an elongate body 32 having a peripheral surface 34, a proximal end 36 and a distal end 38. The endocardial lead 24 also includes one or more defibrillation coil electrodes and one or more pacing/sensing electrodes. In one embodiment, the endocardial lead 24 has a first defibrillation coil electrode 40, a first pacing/sensing electrode 42 and a
25 second defibrillation coil electrode 44 attached to the peripheral surface 34 of the elongate body 32.

In one embodiment the first defibrillation coil electrode 40 and the second defibrillation coil electrode 44 are helically wound spring electrodes as are known in the art. The first defibrillation coil electrode 40 and the second
30 defibrillation coil electrode 44 have surface areas that are between 200 to 1000 square millimeters, where a surface area of 500 square millimeters for the first defibrillation coil electrode 40 and a surface area of 800 square millimeters for the second defibrillation coil electrode 44 are acceptable values. In an additional

embodiment, the first defibrillation coil electrode 40 and the second defibrillation coil electrode 44 have a helical coil diameter of between 2.5 to 4.0 millimeters and a length in the range of 2 to 6 cm, 3 to 6 cm, 4 to 6 cm, 2 to 4 cm where 3 to 4 cm is an acceptable range.

5 The first defibrillation coil electrode 40 further includes a first end 46 and a second end 48, where the first end 46 is at or near the distal end 38 of the elongate body 32 and the second end 48 is spaced longitudinally along the peripheral surface from the first end 46 of the first defibrillation coil electrode 40 and the distal end 38 of the elongate body 32. In one embodiment the first end
10 46 of the first coil electrode 40 forms a portion of the distal end 38 of the elongate body 32. In an alternative embodiment, the first end 46 of the first coil electrode 40 is spaced longitudinally along the peripheral surface 34 from the distal end 38 by a distance in the range of 0 to 7 millimeters.

 The first pacing/sensing electrode 42 is spaced longitudinally
15 along the peripheral surface 34 from the second end 48 of the first defibrillation coil electrode 40 by a distance in the range of 1 to 10 centimeters, where an acceptable range is between 1 to 3 centimeters. In one embodiment, the spacing of the first defibrillation coil electrode 40 and the first pacing/sensing electrode 42 is to afford positioning the first defibrillation coil 40 and the first
20 pacing/sensing electrode 42 in the right ventricle 50 of the heart 28. In one embodiment, the first defibrillation coil electrode 40 is implanted into the apical location of the right ventricle 50 such that the first defibrillation coil electrode 40 is positioned longitudinally adjacent the septal location of the right ventricle 50 of the heart 28 and the first pacing/sensing electrode 42 is in physical contact
25 with the septal wall of the right ventricle 50.

 The second defibrillation coil electrode 44 is spaced
longitudinally along the peripheral surface 34 from the first pacing/sensing
electrode 42 by a distance in the range of 8 to 15 centimeters. In one
embodiment, the spacing of the second defibrillation coil electrode 44 and the
30 first defibrillation coil electrode 40 is to afford positioning the second defibrillation coil electrode 44 within a right atrial chamber 52 or a major vein 54 leading to the right atrial chamber 52 when the first defibrillation coil electrode 40 and the first pacing/sensing electrode 42 are positioned within the

right ventricular chamber 50. In one embodiment, the major vein 54 leading to the heart right atrial chamber 52 is the superior vena cava.

Referring now to Figures 2 and 3 there is shown one embodiment of the endocardial lead 24 according to the present invention. A first electrical conductor 56 is shown extending longitudinally within the elongate body 32 from a first contact end 58 at the proximal end 36 and is electrically connected to the first defibrillation coil electrode 40. A second electrical conductor 60 is also shown extending longitudinally within the elongate body 32 from a second contact end 62 at the proximal end 36 and is electrically connected to the first pacing/sensing electrode 42. Finally, a third electrical conductor 64 is shown extending longitudinally within the elongate body 32 from a third contact end 66 at the proximal end 36 and is electrically connected to the second defibrillation coil electrode 44. In one embodiment, the first contact end 58, the second contact end 62 and the third contact end 66 are tubular or solid metallic pins which are constructed of titanium, stainless steel, or MP35N.

The endocardial lead has at least one stylet lumen extending longitudinally in the elongate body 32. In one embodiment, the elongate body 32 has a first stylet lumen 68 and a second stylet lumen 70, where the first stylet lumen 68 extends from a first inlet end 72 at the proximal end 36 to the distal end 38. The first stylet lumen 68 is adapted to receive a guide stylet for stiffening and shaping the endocardial lead 24 during the insertion of the endocardial lead 24 into the heart 28. The second stylet lumen 70 extends from a second inlet end 74 at the proximal end 36 to the first pacing/sensing electrode 42. In one embodiment, the second stylet lumen 70 is formed by the second electrical conductor 60, which has an elongate helical coil configuration as is known in the art.

In an additional embodiment, the first pacing/sensing electrode 42 includes a retaining element 76, where the retaining element 76 is adapted to be embedded in the right ventricle 50 of the heart 28. The retaining element 76 is designed to secure the first pacing/sensing electrode 42 and the elongate body 32 of the endocardial lead 24 to the heart 28. In one embodiment, the retaining element 76 is intended to secure the first pacing/sensing electrode 42 and the

elongate body 32 of the endocardial lead 24 at an endocardial position within the right ventricle 50 of the heart 28.

In one embodiment, the retaining element 76 is a straight segment of wire. The straight segment of wire has a proximal and a distal end, where the distal end is sharpened to a point and further includes a retaining barb. The retaining barb at the distal end projects away from the peripheral surface of the straight wire and toward the proximal end of the straight wire and is intended to engage and embed into the tissue of the heart. In an additional embodiment, the retaining element 76 is a wire shaped into a helical cork-screw like projection, where the wire has a proximal end and a distal end. In one embodiment, the distal end is sharpened to a point which is adapted to engage and embed into the ventricular tissue of the heart. In an additional embodiment, the proximal end of the retaining element 76 is secured within the first pacing/sensing electrode 42 by welding the proximal end to the first pacing/sensing electrode. In an alternative embodiment, the proximal end of the retaining element 76 is physically secured to the first pacing/sensing electrode 42 by engaging the proximal end and the first pacing/sensing electrode 42 so as to create a friction fit between the two elements.

In a further embodiment, the retaining element 76 forms a portion of the first pacing/sensing electrode, where the wire retaining element emanates from and extends away from an outer surface of the first pacing/sensing electrode 42. In an additional embodiment, the helical wire of the retaining element 76 extends around the peripheral surface of the first pacing/sensing electrode, extending away from the outer surface of the first pacing/sensing electrode. In an alternative embodiment, the retaining element 76 is a hooked projection having a sharpened distal end which is used to engage the tissues of the right ventricle of the heart and to secure the first pacing/sensing electrode 42 and the elongate body 32 to the heart 28.

Referring now to Figures 4 and 5, there is shown an additional embodiment of an endocardial lead 24, in which the elongate body 32 of the endocardial lead 24 further includes an arc-shaped end portion 80. In one embodiment, the arc-shaped end portion 80 curves away from the long-axis of the elongate body 32 to create a "J-tip" at the distal end 38 of the endocardial

lead 24. In an alternative embodiment, the arc-shaped end portion 80 curves away from the long-axis of the elongate body 32 to create a "L-tip" at the distal end 38 of the endocardial lead 24, where the distal end 38 of the elongate body 32 is positioned perpendicularly to the long-axis of the elongate body 32. The arc-shaped end portion 80 is adapted to be positioned within and adjacent to the apex 82 of the right ventricle 50.

In one embodiment, the arc-shaped end portion 80 curves away from the longitudinal axis of the proximal end 36 of the elongate body 32 in a direction that is opposite the side on which the first pacing/sensing electrode 42 is positioned. In one embodiment, this configuration of the endocardial lead 24 allows the first pacing/sensing electrode 42 to be implanted or positioned along the septal wall 84 of the right ventricle 50. As the elongate body 32 extends down and adjacent the septal wall 84 the arc-shaped end portion 80 begins to curve or deflect away from the septal wall 84 as the elongate body 32 extends into the apex 82 of the right ventricle 50. The arc-shaped end portion 80 is adapted to be positioned in the apex 82 of the right ventricle 50. As a result, the first defibrillation coil electrode 40 is located in the apex 82 and along the endocardial wall 86 of the right ventricle 50. Depending upon the length of the first defibrillation coil electrode 40, a portion of the electrode extends along the endocardial wall 86 of the right ventricle 50 from the region of the apex 82 of the right ventricle 50.

In an alternative embodiment, the arc-shaped end portion 80 curves away from the longitudinal axis of the proximal end 36 of the elongate body 32 in a direction that is perpendicular to the side on which the first pacing/sensing electrode 42 is positioned. In an additional embodiment, the arc-shaped end portion 80 curves away from the longitudinal axis of the proximal end 36 of the elongate body 32 in any direction that is between being opposite or perpendicular to the side on which the first pacing/sensing electrode 42 is positioned on the peripheral surface 34 of the elongate body 32. Generally, this configuration of the endocardial lead 24 allows the first pacing/sensing electrode 42 to be implanted or positioned along the septal wall 84 of the right ventricle 50. As the elongate body 32 extends down and adjacent the septal wall 84 the arc-shaped end portion 80 begins to curve or deflect away from the longitudinal

axis of the elongate body 32 along the septal wall as the elongate body 32 extends into the apex 82 of the right ventricle 50. The arc-shaped end portion 80 is adapted to be positioned in the apex 82 of the right ventricle 50 so that the first defibrillation coil electrode 40 is located along both the endocardial wall 86 and the septal wall 84 in the region of the apex 82 of the right ventricle 50. Depending upon the length of the first defibrillation coil electrode 40, a portion of the electrode extends along the endocardial wall 86 of the right ventricle 50 from the region of the apex 82 of the right ventricle 50.

In one embodiment of creating the arc-shaped end portion 80 of the endocardial lead 24, the first defibrillation coil electrode 40 is formed with a mechanical bias in the electrode structure. In one embodiment, the mechanical bias in the first defibrillation coil electrode 40 is imparted into the electrode during the winding of the electrode. In an alternative embodiment, the mechanical bias is created by mechanically deforming the electrode after it has been wound. In an alternative embodiment, the polymer structure of the elongate body 32 is modified to create the arc-shaped end portion 80. In one embodiment, the arc-shaped end portion 80 is constructed of a polymer having an enhanced stiffness relative to the remainder of the elongate body 32. In an alternative embodiment, the arc-shaped end portion 80 is molded into the elongate body 32 during the construction of the elongate body 32.

In one embodiment, the curvature of the arc-shaped end portion 80 generally conforms to the curvature of the apex 82 region. This radius of curvature maximizes direct contact between the first defibrillation coil electrode 40 and the endocardial tissue of the right ventricle 50. Because the shape of diseased hearts varies considerably, an optimized radius of curvature will be determined on a patient by patient basis.

In one embodiment, the arc-shaped end portion 80 has a semicircular shape. In an alternative embodiment, the arc-shaped end portion 80 has a parabolic shape. In an additional embodiment, the arc-shaped end portion 80 has a small radius of curvature which creates an abrupt angular deflection in the elongate body of the endocardial lead 24. In one embodiment, the radius of curvature creates an angle of between approximately 10 to 70 degrees relative to a longitudinal axis of the distal end 38 and a longitudinal axis of the proximal

end 36 of the elongate body 32. In an alternative embodiment, the radius of curvature is in the range of 0.25 to 1 cm, 0.5 to 1 cm, 1 to 2 cm, 1 to 3 cm when a radius of curvature of approximately 1 cm is an acceptable value.

Referring now to Figure 6 (A-C), there is shown an additional
5 embodiment of the endocardial lead 24 in which the peripheral surface 34 of the elongate body 32 further defines an electrode housing 100 having walls defining an opening therethrough, and where the electrode housing 100 is adapted to sheathe the first pacing/sensing electrode 42 and through which the first
10 pacing/sensing electrode 42 extends to engage the right ventricular chamber 50 of the heart 28.

In one embodiment, the electrode housing 100 is attached to and projects away from the peripheral surface 34 of the elongate body 32. The electrode housing 100 has a first wall portion 102 that partially encircles and projects away from the peripheral surface 34 in an arcuate fashion until it reaches
15 an upper limit 104 at which point the first wall portion 102 becomes parallel with the longitudinal axis of the elongate body 32. In one embodiment, the cross-sectional shape of the electrode housing 100 at the upper limit 104 of the first wall portion 102 is that of a partial ellipse.

The electrode housing 100 also includes a second wall portion
20 106, where the second wall portion 106 is positioned essentially perpendicular to the first wall portion 102 so that the second wall portion 106 projects from the upper limit 104 of the first wall portion 102 to a portion of the peripheral surface 34 of the elongate body 32. The second wall portion 106 also defines the opening 108 through the electrode housing 100, where the opening 108 through
25 the electrode housing 100 is coupled to an opening through the peripheral surface 34 of the elongate body 32. The second electrical conductor 60 extends through the opening in the elongate body 32 and into the opening 108 defined by the second wall portion 106 of the electrode housing 100. In one embodiment, the second wall portion 106 defines a tubular shaped opening 108 through the
30 electrode housing 100.

In one embodiment, the second electrical conductor 60 is coupled to and makes an electrical connection with a moveable element 110 which is housed within the opening 108 of the electrode housing 100. The moveable

element 110 has an outer surface 112, an inner surface 114 and a circumferential surface 116, where the circumferential surface 116 is sealed against the second wall portion 106 of the opening 108.

In one embodiment, the moveable element 110 is intended to
5 move longitudinally within the opening 108 from a first or recessed position 118 to a second or extended position 120 and also to rotate on the circumferential surface 116 due to force applied to the inner surface of the sleeve by a guide stylet inserted through the second stylet lumen 70, where the second stylet lumen 70 is adapted to receive a stylet for extending and rotating the first
10 pacing/sensing electrode 42 to embed the retaining element 76 of the first pacing/sensing electrode 24 into the right ventricle 50 of the heart 28.

The second electrical conductor 60 is secured to the elongate body 32 at the location where it emerges from the opening through the peripheral surface 34 of the elongate body 32 into the opening 108 through the electrode
15 housing 100. The helical coil construction of the second electrical conductor 60 then allows the conductor to extend in a spring like fashion as the moveable element 110 moves between the first position 118 and the second position 120.

In one embodiment, the first pacing/sensing electrode 42 is coupled to the outer surface 112 of the moveable element 110. In the first
20 position 118 of the moveable element 110, the first pacing/sensing electrode 42 and the retaining element 76 are housed within the opening 108 in the electrode housing 100. After the moveable element 110 is advanced to the second position 120, both the retaining element 76 and the first pacing/sensing electrode 42 extend a predetermined distance beyond the second wall portion 106 of the
25 electrode housing 100. In one embodiment, up to 3 centimeters is an acceptable predetermined distance. In one embodiment, the retaining element 76 and the first pacing/sensing electrode 42 extend beyond the second wall portion 106 in plane that is essentially parallel to the longitudinal axis of the elongate body 32. In an alternative embodiment, the retaining element 76 and the first
30 pacing/sensing electrode 42 extends beyond the second wall portion 106 in plane having an acute angle (less than 90 degrees) relative to the longitudinal axis of the elongate body 32.

In an additional embodiment, the elongate body further has a plurality of tines 78 at or adjacent the distal end 38, the plurality of tines 78 being circumferentially spaced and projecting both radially away from the peripheral surface 34 and toward the proximal end 36 of the elongate body 32.

- 5 In one embodiment, the plurality of tines is constructed of the same material used to make the elongate body 32 of the endocardial lead 24.

In one embodiment, the elongate body 32 of the endocardial lead 24 is made by extrusion of an implantable polyurethane, silicone rubber or other implantable flexible biocompatible polymer. The length of the elongate body 32
10 of the endocardial lead 24 between the proximal end 36 and the distal end 38 is in the range of between 60 to 120 centimeters. In an additional embodiment, the elongate body 32 has a diameter of less than or equal to 4 millimeters. The electrical conductors 56, 60 and 64 are made of a MP35N nickel-cobalt alloy, or other electrical conductor metal as are known in the art. The first defibrillation
15 coil electrode 40, the second defibrillation coil electrode 44, the first pacing/sensing electrode 42, the moveable element 110, and the retaining element 76 are made of an implantable metal such as platinum/iridium alloys, titanium or other implantable metals as are known in the art.

Experimental data indicate that the use of the endocardial lead 24
20 has the potential of reducing a patient's defibrillation strength requirements. Experimental tests on defibrillation energy requirements using both the endocardial lead 24 of the present invention and an endocardial lead sold under the trademark ENDOTAK (Cardiac Pacemaker, Inc./ Guidant Corporation, St. Paul, MN), in porcine and canine models indicate that the use of the endocardial
25 lead 24 reduced defibrillation delivered energy requirements by 26% as compared to the use of the ENDOTAK lead. Also, the use of the endocardial lead 24 and the ENDOTAK lead in the same animal models showed that the use of the endocardial lead 24 reduced the average peak current requirements of 22% as compared to the use of the ENDOTAK lead.

30 The experimental endocardial defibrillation systems incorporated either the single-pass ENDOTAK or the endocardial lead 24 of the present invention with an implantable cardioverter/defibrillator sold under the trademark MINI II (Cardiac Pacemaker, Inc./ Guidant Corporation, St. Paul, MN), shell

electrode to create a defibrillation electrode system sold under the trademark TRIAD, (Cardiac Pacemaker, Inc./ Guidant Corporation, St. Paul, MN). Both leads consisted of an approximately 3.4 cm long, 0.110 inch diameter distal and a 6.8 cm long, 0.110 inch diameter proximal tri-filar DBS spring shocking electrodes. The ENDOTAK lead had a standard porous tip pace/sense electrode with a tip-to-shocking electrode length of approximately 1.2 cm. Conversely, the endocardial lead 24 had the shocking electrode positioned at the end of the elongate body 32 with the first pacing/sensing electrode 42 approximately 1.2 cm proximal to the shocking electrode. In one embodiment, the first

10 pacing/sensing electrode 42 consisted of a miniaturized electrode position within the helical coil wound around the outside diameter of the electrode. For purposes of the experimental procedure, the elongate body 32 further includes a curved portion, where the curved portion is positioned between the proximal end 36 and the distal end 38 of the elongate body 32. The curved portion has an

15 outer radial surface and an inner radial surface, where the outer radial surface generally has a larger radius of curvature than the inner radial surface. The first pacing/sensing electrode 42 was positioned on the outer radial surface of the curved portion so that the first pacing/sensing electrode 42

20 extended beyond the peripheral surface 34 of the elongate body 32 along an axis that is essentially parallel with a longitudinal axis of the proximal end 36 of the elongate body 32 to engage the tissue of the heart 28. The curved portion of the endocardial lead 24 created an approximately 60 degree arc relative to a longitudinal axis of the distal end 38 and a longitudinal axis of the proximal end 36 of the elongate body 32 to facilitate septal positioning and to serve as a

25 platform for the first pacing/sensing electrode 42.

Pacing and sensing characteristics and defibrillation strength requirements for each lead system were determined in six swine. Under fluoroscopic guidance, both lead systems were positioned into the right ventricular apex through a left external jugular venotomy. Once apically placed,

30 each lead was advanced until the right ventricular shocking electrode was positioned into the anterior groove of the right ventricular out-flow tract against the septum. The MINI II shell electrode was subcutaneously implanted in the

left pectoral region. For defibrillation trials, the right ventricular shocking electrode served as the cathode.

Pacing thresholds (0.5 ms pulse widths), impedances and sensing characteristics (R-wave amplitudes) were determined prior to the defibrillation trials using a SEAMED external stimulator (Redmond, WA). Defibrillation strength requirements (delivered energy, peak voltage and peak current) and system impedances for each lead system were determined using 80% fixed-tilt biphasic shocks generated from a LABVIEW directed current amplifier (National Instrument, Austin, TX). The defibrillation requirements, pacing thresholds and sensing characteristics of the two lead systems were compared using paired t tests.

Defibrillation strength requirements for the endocardial lead 24 was lower than with the ENDOTAK system. Delivered energy, peak voltage and peak current requirements were 32%, 17% and 25%, ($p < 0.01$) respectively, lower with the endocardial lead 24 when applied to the TRIAD system as compared to the ENDOTAK TRIAD system. Although not statistically significant with the paired t-test, pacing and sensing characteristics of the endocardial lead 24 were different from the ENDOTAK system. Sensed R-wave amplitudes were 14% ($p > 0.05$) lower with the endocardial lead 24 system than with the ENDOTAK system. Pacing thresholds were 38% lower (0.3V, $p > 0.05$) with the ENDOTAK passive electrode than with the retractable miniaturized positive fixation electrode of the endocardial lead 24 system. The endocardial lead 24 test lead system impedance was 12% higher than the ENDOTAK system.

Referring now to Figure 7, there is shown one embodiment of an electronics block diagram of the cardioverter/defibrillator 22. The cardioverter/defibrillator 22 includes electronic control circuitry 200 for receiving cardiac signals from the heart 28 and delivering electrical energy to the heart 28. In one embodiment, the electronic control circuitry 200 includes terminals, labeled with reference numbers 202, 204, 206, and 208 for connection to the first defibrillation coil electrode 40, the first pacing/sensing electrode 42, and the second defibrillation coil electrode 44 attached to the surface of the endocardial lead 24.

The electronic control circuitry 200 of the cardioverter/defibrillator 22 is encased and hermetically sealed in a housing 210 (Figures 1 and 5) suitable for implanting in a human body 26. In one embodiment, titanium is used for the housing 210, however, other biocompatible housing materials as are known in the art may be used. A connector block 212 (Figures 1 and 5) is additionally attached to the housing 210 of the cardioverter/defibrillator 22 to allow for the physical and the electrical attachment of the endocardial lead 24 and the electrodes to the cardioverter/defibrillator 22 and the encased electronic control circuitry 200.

10 The electronic control circuitry 200 of the cardioverter/defibrillator 22 is a programmable microprocessor-based system, with a microprocessor 214 a memory circuit 216, which contains parameters for various pacing and sensing modes, and stores data indicative of cardiac signals received by the electronic control circuitry 200. A transmitter circuit 218 is additionally coupled to the electronic control circuitry 200 and the memory circuit 214 to allow the cardioverter/defibrillator 22 to communicate with an external controller unit 220. In one embodiment, the transmitter circuit 218 and the external controller unit 220 use a wire loop antenna 222 and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data to and from the external controller unit 220 and the electronic control circuitry 200. In this manner, programming commands or instructions are transferred to the microprocessor 214 of the cardioverter/defibrillator 22 after implant, and stored cardiac data pertaining to sensed arrhythmic events within the heart 28 and subsequent therapy, or therapies, applied to correct the sensed arrhythmic event are transferred to the external controller unit 220 from the cardioverter/defibrillator 22.

In the cardioverter/defibrillator 22 of Figure 7, the first defibrillation coil electrode 40 and the first pacing/sensing electrode 42 are coupled to a sense amplifier 224, whose output is shown connected to an R-wave detector 226. These components serve to sense and amplify the QRS waves of the heart, and apply signals indicative thereof to the microprocessor 214. Among other things, microprocessor 214 responds to the R-wave detector 226 by providing pacing signals to a pace output circuit 228, as needed according to the

programmed pacing mode. Pace output circuit 228 provides output pacing signals to terminals 202 and 204, which connect to the first pacing/sensing electrode 42 and the first defibrillation coil electrode 40, for bipolar cardiac pacing. In an alternative embodiment, the pace output circuit 228 provides
5 output pacing signals to terminal 202 and to the housing 210 of the cardioverter/defibrillator 22 to provide both unipolar sensing of the heart 28 and unipolar pacing of the heart 28.

The first defibrillation coil electrode 40 and the second defibrillation coil electrode 44 are coupled to a sense amplifier 230, whose
10 output is connected to a cardiac morphology detector 232. These components serve to sense and amplify the QRS-waves of the cardiac cycle from the ventricular region of the heart 28, and apply signals indicative thereof to the microprocessor 214. In one embodiment, the cardiac morphology detector 232 includes an analog filter for filtering cardiac signal noise sensed by the
15 electrodes. The cardiac signals are then A/D converted into a digital signal and subsequently received by the microprocessor 214.

Among other things, microprocessor 214 responds to the sensed QRS-waves of the cardiac cycle from the sense amplifier 230 applied to the morphology detector 232 by providing pacing signals to the pace output circuit
20 228, as needed according to the programmed pacing mode. Pace output circuit 228 provides output pacing signals to terminals 202 and 204, which connect to the first pacing/sensing electrode 42 and the first defibrillation electrode 40, for bipolar pacing or to the first pacing/sensing electrode 42 and the housing 210 for unipolar pacing as previously described.

25 The microprocessor 214 also responds to the cardiac signals sensed within the heart 28 using the endocardial lead 24 by providing signals to cardioversion/defibrillation output circuitry 234 to provide either cardioversion or defibrillation electrical energy to the heart 28 depending upon nature of the arrhythmia sensed by the cardioverter/defibrillator 22. Power to the
30 cardioverter/defibrillator 22 is supplied by an electrochemical battery 236 that is housed within the cardioverter/defibrillator 22.

In one embodiment, the cardioversion or defibrillation electrical energy pulses delivered to the heart 28 are either a monophasic, biphasic or

multiphasic pulses of electrical energy, as are known in the art. In an additional embodiment, more than one of the cardioversion or defibrillation electrical energy pulses are delivered to the heart, where the pulses are delivered either simultaneously or sequentially. In one embodiment, the defibrillation electrical energy is delivered between first defibrillation coil electrode 40 and the second defibrillation coil electrode 44 and the housing 210 of the cardioverter/defibrillator 22. In a further embodiment, the first defibrillation coil electrode 40 is a cathode terminal and the second defibrillation coil electrode 44 and the housing 210 are anode terminals. In an alternative embodiment, cardioversion or defibrillation electrical energy is delivered between the first defibrillation coil electrode 40 and the second defibrillation coil electrode 44, where, in one embodiment, the first defibrillation coil electrode 40 is a cathode terminal and the second defibrillation coil electrode 44 is an anode terminal. In another embodiment, additional defibrillation electrodes, such as subcutaneous patch electrode, epicardial defibrillation electrodes and the like can be incorporated into and added to the cardioverter/defibrillator 22 to allow for further defibrillation electrical energy pathways.

Referring now to Figure 8, there is shown an additional embodiment of an endocardial lead 24, in which the elongate body 32 of the endocardial lead 24 includes a curved portion 300. The curved portion 300 is positioned between the proximal end 36 and the distal end 38 of the elongate body 32. In one embodiment, the curved portion 300 has an outer radial surface 310 and an inner radial surface 320, where the outer radial surface 310 generally has a larger radius of curvature than the inner radial surface 320. In an additional embodiment, the electrode housing 100 is positioned generally on the outer radial surface 310 of the curved portion 300. This configuration allows the first pacing/sensing electrode 42 to extend beyond the peripheral surface 34 of the elongate body 32 along an axis that is essentially parallel with a longitudinal axis of the proximal end 36 of the elongate body 32 to engage the tissue of the heart 28. In an alternative embodiment, the first pacing/sensing electrode 42 to extend beyond the peripheral surface 34 of the elongate body 32 along an axis that has an obtuse angle (greater than 90 degrees) relative to the longitudinal axis of the proximal end 36 of the elongate body 32 to engage the tissue of the heart 28.

The curved portion 300 of the endocardial lead 24 creates an angle of between approximately 45 to 60 degrees relative to a longitudinal axis of the distal end 38 and a longitudinal axis of the proximal end 36 of the elongate body 32. In one embodiment, the curved portion 300 of the elongate body is created by a mechanical bias in one or more of the first electrical conductor 56, the second electrical conductor 60 or the third electrical conductor 64. In an additional embodiment, the polymer structure of the elongate body 32 is modified to create the curved portion 300. In one embodiment, the curved portion 300 is constructed of a polymer having an enhanced stiffness relative to the remainder of the elongate body 32. In an alternative embodiment, the curved portion 300 is molded into the elongate body 32 during the construction of the elongate body 32.

Referring now to Figure 9, there is shown an additional embodiment of the endocardial lead 24 according to the present invention. The endocardial lead 24 comprises an elongate body 32 having a peripheral surface 34, a proximal end 36 and a distal end 38. The endocardial lead 24 also includes one or more defibrillation coil electrodes and one or more pacing/sensing electrodes. In one embodiment, the endocardial lead 24 has a first defibrillation coil electrode 40, a first pacing/sensing electrode 400 and a second defibrillation coil electrode 44 attached to the peripheral surface 34 of the elongate body 32.

In one embodiment the first defibrillation coil electrode 40 and the second defibrillation coil electrode 44 are helically wound spring electrodes as are known in the art. The first defibrillation coil electrode 40 further includes a first end 46 and a second end 48, where the first end 46 is at or near the distal end 38 of the elongate body 32 and the second end 48 is spaced longitudinally along the peripheral surface from the first end 46 of the first defibrillation coil electrode 40 and the distal end 38 of the elongate body 32. In one embodiment the first end 46 of the first coil electrode 40 forms a portion of the distal end 38 of the elongate body 32. In an alternative embodiment, the first end 46 of the first coil electrode 40 is spaced longitudinally along the peripheral surface 34 from the distal end 38 by a distance in the range of 0 to 7 millimeters.

The first pacing/sensing electrode 400 is spaced longitudinally along the peripheral surface 34 from the second end 48 of the first defibrillation

coil electrode 40 by a distance in the range of 1 to 10 centimeters, where an acceptable range is between 1 to 3 centimeters. In one embodiment, the spacing of the first defibrillation coil electrode 40 and the first pacing/sensing electrode 400 is to afford positioning the first defibrillation coil 40 and the first

5 pacing/sensing electrode 400 in the right ventricle 50 of the heart 28. In one embodiment, the first defibrillation coil electrode 40 is implanted directly along the septal wall of the right ventricle 50 such that the first defibrillation coil electrode 40 is positioned longitudinally adjacent the septum of the right ventricle 50 of the heart 28 and the first pacing/sensing electrode 400 is in

10 physical contact with a wall of the right ventricle. In one embodiment, the pacing electrode is positioned such that it is in contact with the ventricular septum of the heart. In an alternative embodiment, the first defibrillation coil electrode 40 is implanted directly along the apex location of the right ventricle 50 such that the first defibrillation coil electrode 40 is positioned longitudinally

15 adjacent the apex location of the right ventricle 50 of the heart 28 and the first pacing/sensing electrode 400 is in physical contact with a wall of the right ventricle. In one embodiment, the pacing electrode is positioned such that it is in contact with the ventricular septum of the heart.

The second defibrillation coil electrode 44 is spaced

20 longitudinally along the peripheral surface 34 from the first pacing/sensing electrode 400 by a distance in the range of 8 to 15 centimeters. In one embodiment, the spacing of the second defibrillation coil electrode 44 and the first defibrillation coil electrode 40 is to afford positioning the second defibrillation coil electrode 44 within a right atrial chamber 52 or a major vein

25 leading to the right atrial chamber 52 when the first defibrillation coil electrode 40 and the first pacing/sensing electrode 400 are positioned within the right ventricle chamber 50. In one embodiment, the major vein leading to the heart right atrial chamber 52 is the superior vena cava.

Figure 9 shows one embodiment in which the elongate body 32 of

30 the endocardial lead 24 includes a curved portion 300. The curved portion 300 is positioned between the proximal end 36 and the distal end 38 of the elongate body 32. The curved portion 300 allow the endocardial lead 24 to be implanted within the heart 28 with the first pacing/sensing electrode 400 engaging the

tissue of the heart 28 while the remaining distal portion of the endocardial lead 24, including the first defibrillation coil electrode 40, is positioned adjacent the endocardial wall of the right ventricle, where the first defibrillation coil electrode 40 is in the apex of the right ventricle.

5 The curved portion 300 of the endocardial lead 24 creates an angle of between approximately 45 to 60 degrees relative to a longitudinal axis of the distal end 38 and a longitudinal axis of the proximal end 36 of the elongate body 32. In one embodiment, the curved portion 300 of the elongate body is created by a mechanical bias in one or more of the first electrical conductor 56,
10 the second electrical conductor 60 or the third electrical conductor 64. In an additional embodiment, the polymer structure of the elongate body 32 is modified to create the curved portion 300. In one embodiment, the curved portion 300 is constructed of a polymer having an enhanced stiffness relative to the remainder of the elongate body 32. In an alternative embodiment, the curved
15 portion 300 is molded into the elongate body 32 during the construction of the elongate body 32.

 In one embodiment, the curved portion 300 has an outer radial surface 310 and an inner radial surface 320, where the outer radial surface 310 generally has a larger radius of curvature than the inner radial surface 320. The
20 first pacing/sensing electrode 400 is positioned generally on the outer radial surface 310 of the curved portion 300. This configuration allows the first pacing/sensing electrode 400 to extend beyond the peripheral surface 34 of the elongate body 32 to engage the tissue of the heart 28 when the endocardial lead 24 is positioned within the heart 28. In one embodiment, the first pacing/sensing
25 electrode 400 and the first defibrillation coil electrode 40 are implanted within the heart such that both the first pacing/sensing electrode 400 and the first defibrillation coil electrode 40 are located within the right ventricle with the first defibrillation coil electrode 40 in the apex of the right ventricle and the first pacing/sensing electrode 400 on the ventricular septum of the heart.

30 In one embodiment, the first pacing/sensing electrode 400 is a porous woven mesh on the peripheral surface of the elongate body as is shown in Figure 9. The porous woven mesh is created from implantable metal wire such as platinum/iridium alloys, titanium or other implantable metals as are known in

the art. In one embodiment, the porous woven mesh has a semi-spherical shape and is positioned on the peripheral surface of the elongate body. In an alternative embodiment, the first pacing/sensing electrode is annular and encircles the peripheral surface of the elongate body. In an additional
5 embodiment, the first pacing/sensing electrode is semi-annular and partially encircles the peripheral surface of the elongate body.

In an additional embodiment, the elongate body further has a plurality of tines 78 at or adjacent the distal end 38, the plurality of tines 78 being circumferentially spaced and projecting both radially away from the
10 peripheral surface 34 and toward the proximal end 36 of the elongate body 32. In one embodiment, the plurality of tines is constructed of the same material used to make the elongate body 32 of the endocardial lead 24. In an alternative embodiment, the elongate body 32 of the endocardial lead 24 is physically or chemically treated to promote tissue in-growth. Tissue in-growth allows for the
15 increased stabilization and retention of the endocardial lead 24 after being implanted in the heart 28. In one embodiment, a micro-texturing is created on the surface of the elongate body 32 from chemical or mechanical processing to allow for tissue in-growth.

Referring now to Figures 10 and 11, there is shown an additional
20 embodiment of the endocardial lead 24 according to the present invention. A first electrical conductor 56 is shown extending longitudinally within the elongate body 32 from a first contact end 58 at the proximal end 36 and is electrically connected to the first defibrillation coil electrode 40. A second electrical conductor 60 is also shown extending longitudinally within the
25 elongate body 32 from a second contact end 62 at the proximal end 36 and is electrically connected to the first pacing/sensing electrode 42. A third electrical conductor 64 is shown extending longitudinally within the elongate body 32 from a third contact end 66 at the proximal end 36 and is electrically connected to the second defibrillation coil electrode 44. Finally, a fourth electrical
30 conductor 420 is also shown extending longitudinally within the elongate body 32 from a fourth contact end 422 at the proximal end 36 and is electrically connected to a second pacing electrode 424. In one embodiment, the first contact end 58, the second contact end 62, the third contact end 66, and the

fourth contact end 422 are tubular or solid metallic pins which are constructed of titanium, stainless steel, or MP35N.

The endocardial lead 24 has at least one stylet lumen extending longitudinally in the elongate body 32. In one embodiment, the elongate body 32 has a first stylet lumen 68 and a second stylet lumen 70, where the first stylet lumen 68 extends from a first inlet end 72 at the proximal end 36 to the distal end 38. The first stylet lumen 68 is adapted to receive a guide stylet for stiffening and shaping the endocardial lead 24 during the insertion of the endocardial lead 24 into the heart 28. In one embodiment, a portion of the first stylet lumen 68 is formed by the fourth electrical conductor 420, which has an elongate helical coil configuration as is known in the art. In one embodiment, the elongate helical coil configuration extends longitudinally through the elongate body 32 to a point that is just proximal or adjacent to the second pacing electrode 424. The fourth electrical conductor 420 is then coupled to the second pacing electrode 424. The second stylet lumen 70 extends from a second inlet end 74 at the proximal end 36 to the first pacing/sensing electrode 42. The second stylet lumen 70 is formed by the second electrical conductor 60, which has an elongate helical coil configuration as is known in the art.

In an additional embodiment, the first pacing/sensing electrode 42 and the second pacing electrode 424 provide for bipolar sensing and pacing of the heart 28. In one embodiment, the second pacing electrode 424 is an annular ring electrode that extends completely around the peripheral surface 34 of the elongate body 32. In an alternative embodiment, the second pacing electrode 424 is a semi-annular ring that extends only partially around the peripheral surface 34 of the elongate body 32.

Referring now to Figure 12 of the drawings, there is shown an additional embodiment of the apparatus 20 including the cardioverter/defibrillator 22 physically and electrically coupled to the endocardial lead 24 and to a second endocardial lead 450. The apparatus 20 is implanted in the human body 26 with portions of the endocardial lead 24 and the second endocardial lead 450 inserted into the heart 28 to detect and analyze electrical cardiac signals produced by the heart 28 and to provide electrical energy to the heart 28 under certain predetermined conditions to treat ventricular

arrhythmias, including ventricular tachyarrhythmias and ventricular fibrillation, of the heart 28.

The second endocardial lead 450 comprises an elongate body 452 having a peripheral surface 454, a proximal end 456 and a distal end 458. The second endocardial lead 450 also includes one or more pacing and sensing electrodes. The second endocardial lead 450 is adapted to be releasably attached to the connector block 212 to allow pacing and sensing electrodes attached to the peripheral surface of the second endocardial lead 450 to be physically and electrically coupled to the housing 210 and the electronic control circuitry 200 of the cardioverter/defibrillator 22.

In one embodiment, the second endocardial lead 450 has a distal pacing/sensing electrode 460 attached to the peripheral surface 454 of the elongate body 452. In one embodiment, the distal pacing/sensing electrode 460 is spaced longitudinally along the peripheral surface 454 from the distal end 458 of the elongate body 452 by a distance in the range of 0 to 2 centimeters, where an acceptable range is between 0 to 1 centimeters. In one embodiment, the distal pacing/sensing electrode 460 is an annular, or a semi-annular ring electrode positioned on the elongate body 452 of the second endocardial lead 450. In an alternative embodiment, the distal pacing/sensing electrode 460 is a tip electrode positioned on the distal end 458 of the second endocardial lead 450. The distal pacing/sensing electrode 460 is electrically connected to the electronic control circuitry 200 through a contact end located at the proximal end 456 which is coupled to a first distal electrode electrical conductor extending longitudinally within the elongate body 452 of the second endocardial lead 450.

In one embodiment, the second endocardial lead 450 is positioned on or adjacent a left ventricular epicardial surface 462. In one embodiment, the second endocardial lead 450 is introduced through the coronary sinus vein 464 to an apical branch of the great coronary vein 466 and advanced to a position within the great coronary vein 466, or a tributary vein to the great coronary vein 466, so that the distal pacing/sensing electrode 460 is positioned on or adjacent the left ventricular epicardial surface 462.

In one embodiment, the distal pacing/sensing electrode 460 positioned on or adjacent to the left ventricular epicardial surface 462 and the

housing 210 are used to provide unipolar pacing and sensing of the ventricles of the heart. In an alternative embodiment, the distal pacing/sensing electrode 460 and the first pacing/sensing electrode 42 provide bipolar pacing and sensing of the ventricles of the heart. In an additional embodiment, a second distal
5 pacing/sensing electrode is added to the peripheral surface of the second endocardial lead 450 to provide for bipolar sensing and pacing of the ventricles of the heart.

In an additional embodiment, the elongate body 452 further has a plurality of tines 468 at or adjacent the distal end 458, the plurality of tines 468
10 being circumferentially spaced and projecting both radially away from the peripheral surface 454 and toward the proximal end 456 of the elongate body 452. In one embodiment, the plurality of tines is constructed of the same material used to make the elongate body 452 of the second endocardial lead 450.

The aspects of the invention illustrated herein have been
15 described as having applications for implantable cardioverter/defibrillators, which may include numerous pacing modes as are known in the art. However, the endocardial lead of the present invention is also used in any number of implantable or external medical devices, including external defibrillator/monitor devices. Additionally, the endocardial lead of the present invention alternatively
20 can include additional or fewer defibrillation coil electrodes and/or pacing/sensing electrodes. For example, the endocardial lead can include only the first defibrillation coil electrode 40 and the first pacing/sensing electrode 42, where cardiac sensing is accomplished with unipolar sensing between the first pacing/sensing electrode 42 and housing 210 of the cardioverter/defibrillator 22.
25 Additionally, unipolar defibrillation electrical energy is supplied to the heart between the first defibrillation coil electrode 40 and the housing 210 of the cardioverter/defibrillator 22.

What is claimed is:

1. A lead, comprising:
a lead body extending from a proximal end to a distal end;
5 the proximal end including electrical connections to a pacing electrode
and a defibrillation electrode,
the defibrillation electrode is disposed at the distal end of the lead body;
and
the pacing electrode is disposed on the lead body between the proximal
10 end and the defibrillation electrode.
2. The lead of claim 1, wherein the defibrillation electrode is arcuate.
3. The lead of claim 1, wherein the defibrillation electrode and the pacing
15 electrode are located within three centimeters of each other.
4. The lead of claim 1 or 3, wherein the defibrillation electrode is arcuate.
5. The lead of claim 1 or 2 or 3 or 4, further comprising a second
20 defibrillation electrode disposed on the lead body between the proximal end and
the pacing electrode.
6. The lead of claim 5, wherein the pacing electrode and the second
electrode are located within 8 centimeters of each other.
25
7. The lead of claim 5, wherein the pacing electrode and the second
electrode are located within 15 centimeters of each other.
8. The lead of claims 1 - 7, wherein the pacing electrode includes a
30 retaining element.
9. The lead of claim 8, wherein the retaining element comprises a helical
screw.

10. The lead as in any of claims 1 - 9, in which the lead body further includes a sheathe for the pacing electrode, where the pacing electrode is extendable from within the sheathe.
- 5 11. The lead of claim 10, wherein the lead body is defined by a first longitudinal axis and the pacing electrode is extendable along a second longitudinal axis, and the first longitudinal axis is parallel to the second longitudinal axis.
- 10 12. The lead of claim 10, wherein the distal end of the lead body defines a first longitudinal axis and the pacing electrode is extendable along a second longitudinal axis, and the first longitudinal axis is at an angle of less than 90 degrees relative to the second longitudinal axis.
- 15 13. The lead of claim 1, wherein the lead body has a J-shape.
14. The lead of claim 13, wherein the pacing electrode is disposed on a first side of the lead body, and the J-shape curves away from the first side of the lead body.
- 20 15. The lead of claim 13, wherein the J-shape has a radius of curvature of about 1 to 3 centimeters.
16. The lead as in any of claims 1 - 12, wherein the distal end is defined by a first longitudinal axis, the proximal end is defined by a second longitudinal axis and the first longitudinal axis is disposed at an angle of 45 degrees to 60 degrees relative to the second longitudinal axis.
- 25 17. The lead as in any of claims 1 - 16, in which the pacing electrode comprises a porous mesh.
- 30 18. The lead as in any of claims 1 - 16, in which the pacing electrode has a semi-spherical shape.

19. The lead as in any of claims 1 - 18, in which the lead further comprises a second pacing electrode, where the second pacing electrode is disposed between the proximal end and the pacing electrode.

5

20. The lead as in any of claims 1 - 19, in which the lead further comprises a plurality of tines disposed about the defibrillation electrode.

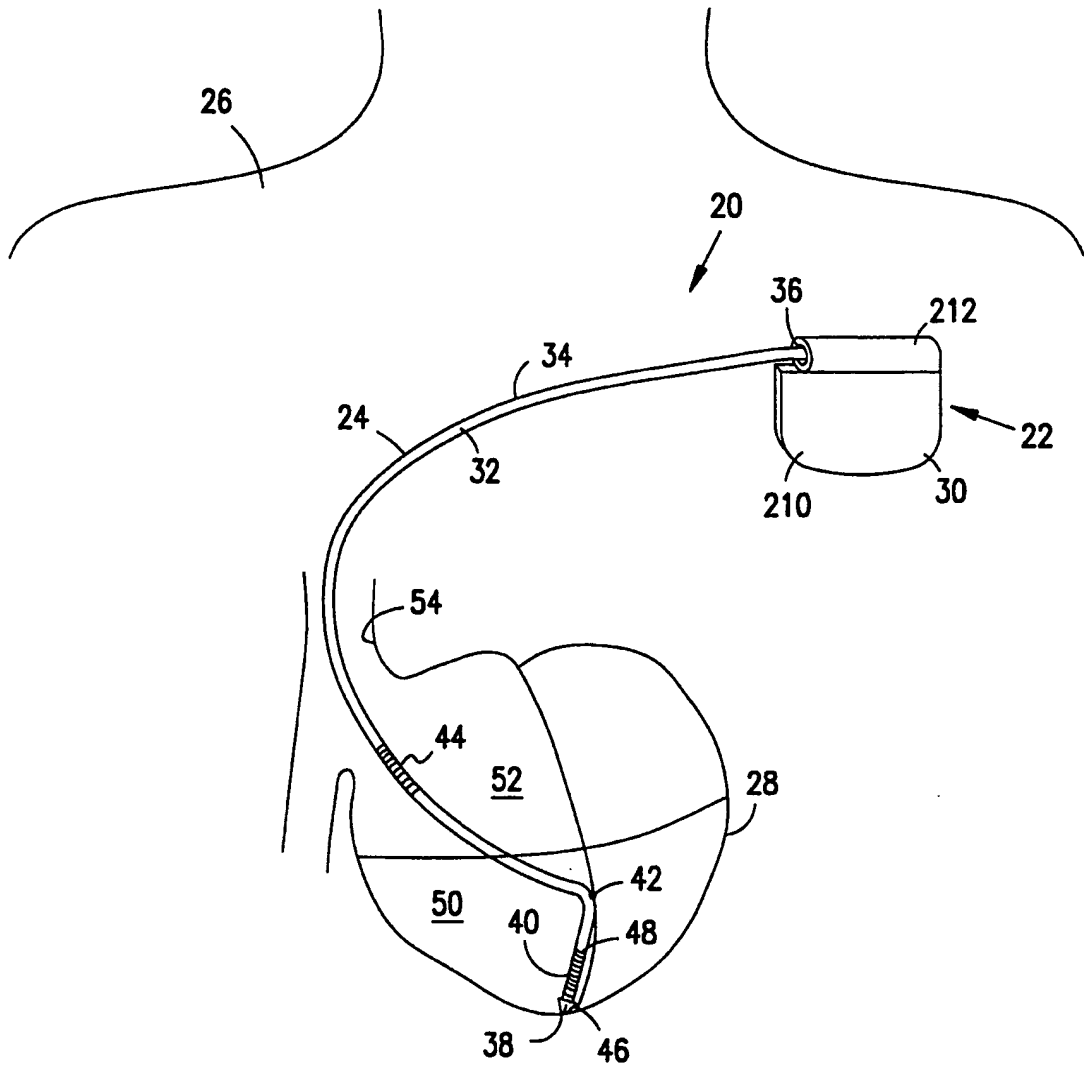
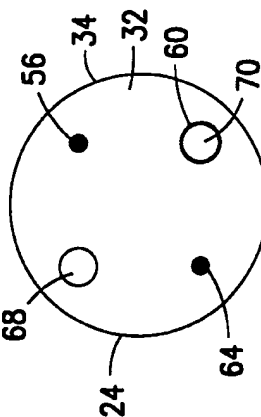
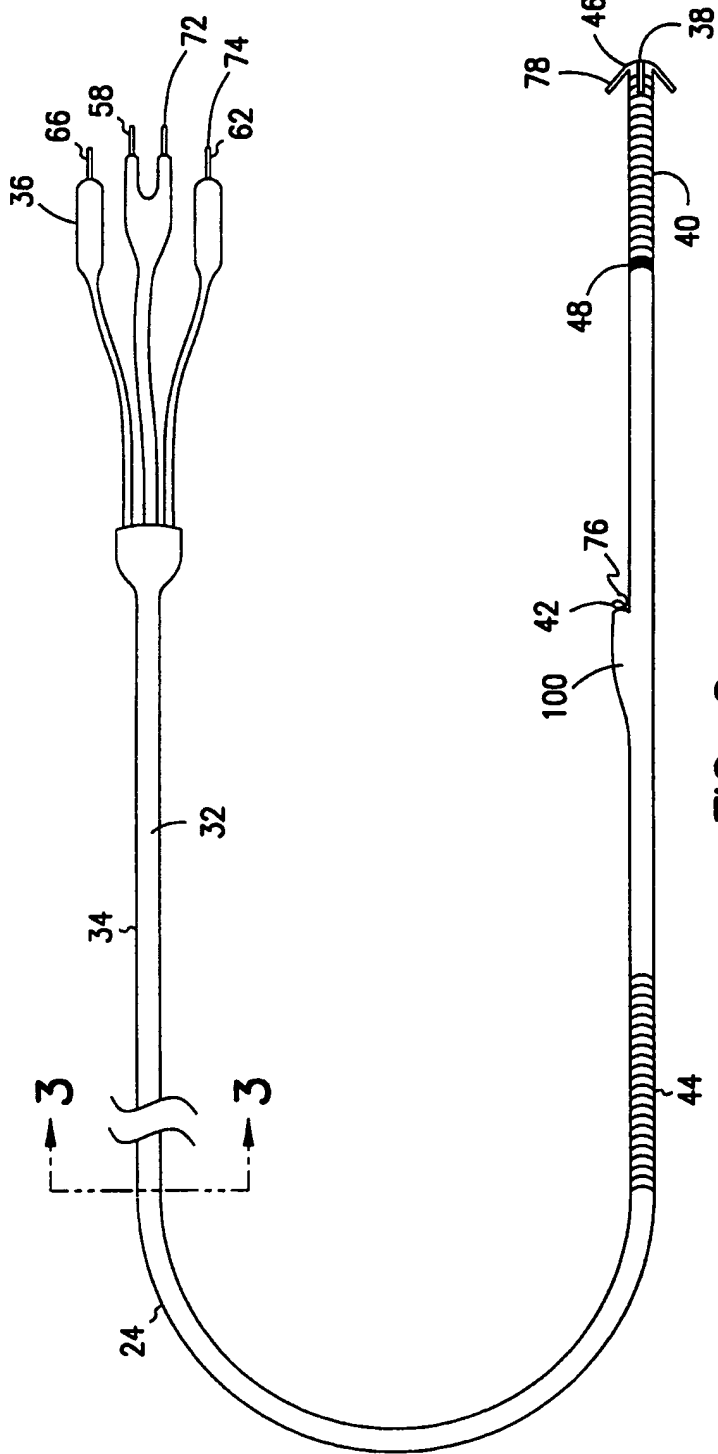


FIG. 1



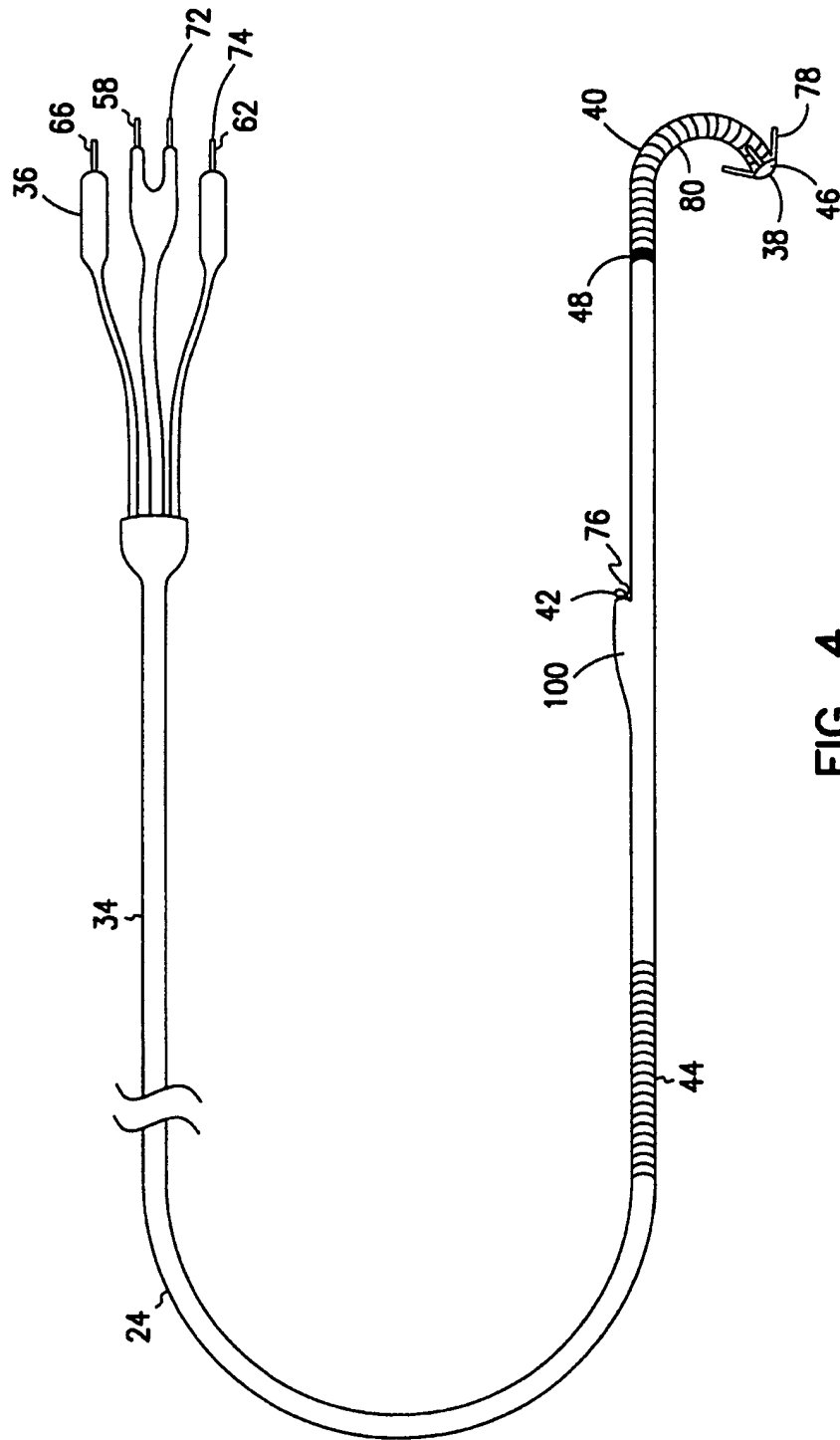


FIG. 4

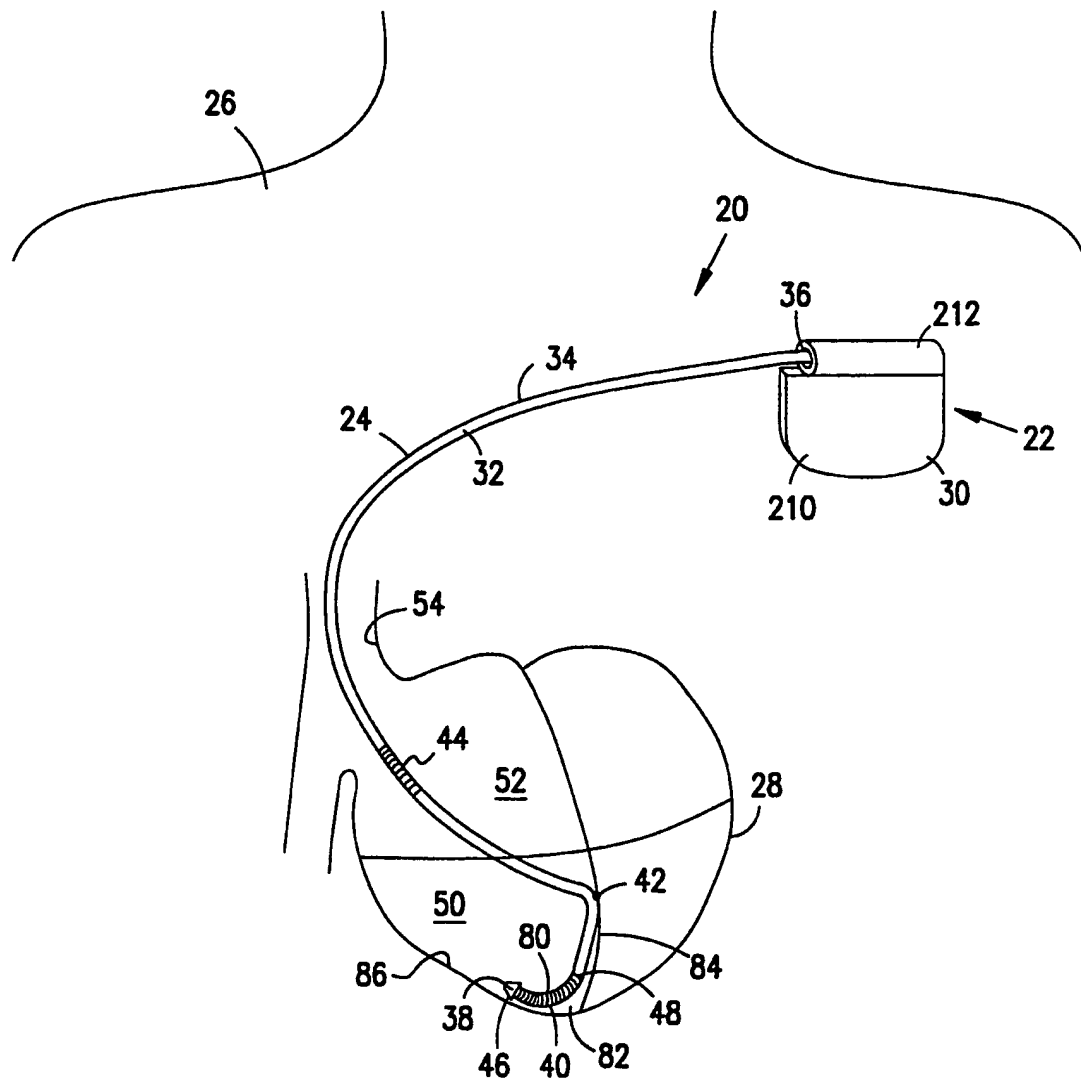


FIG. 5

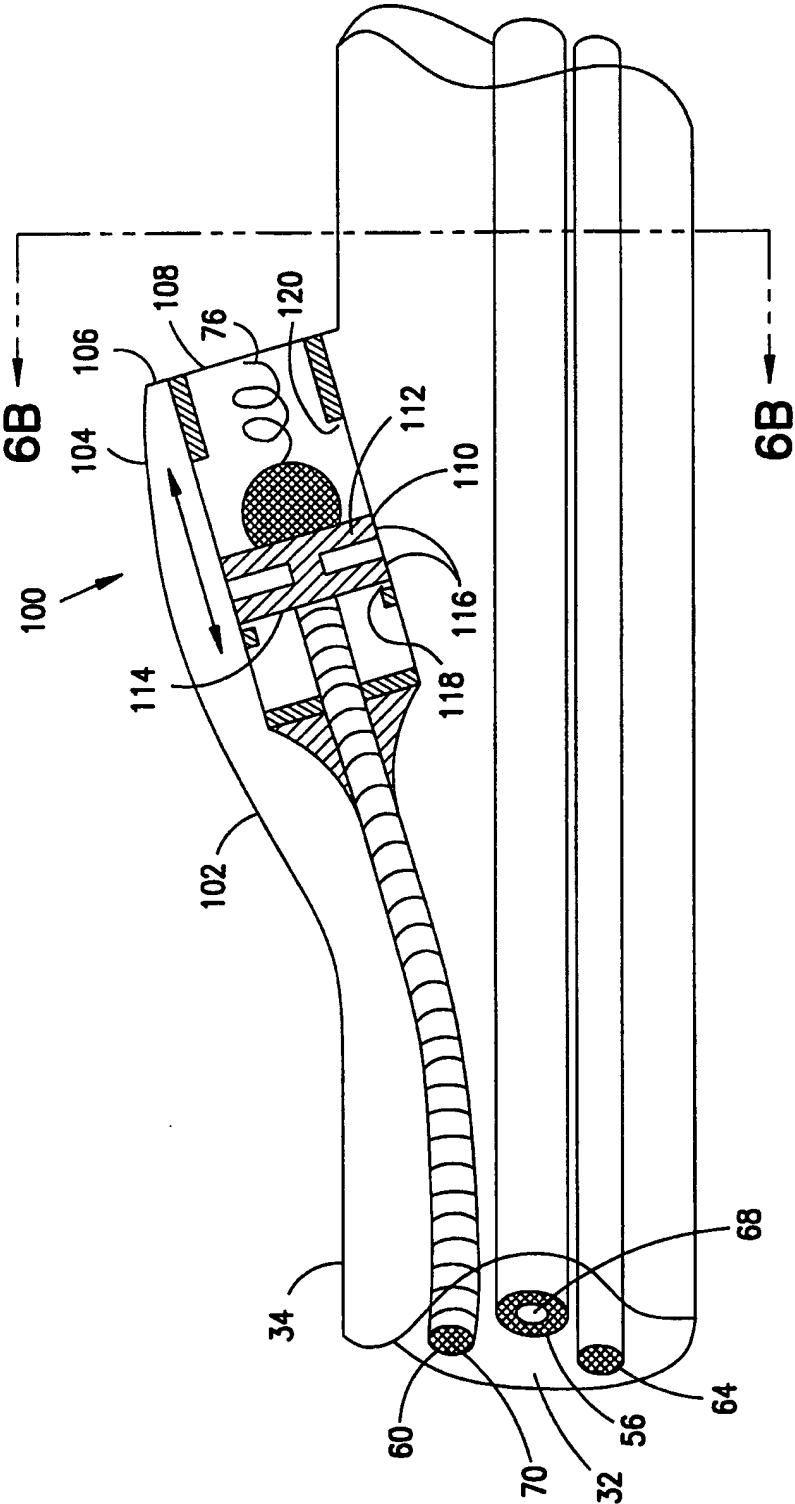


FIG. 6A

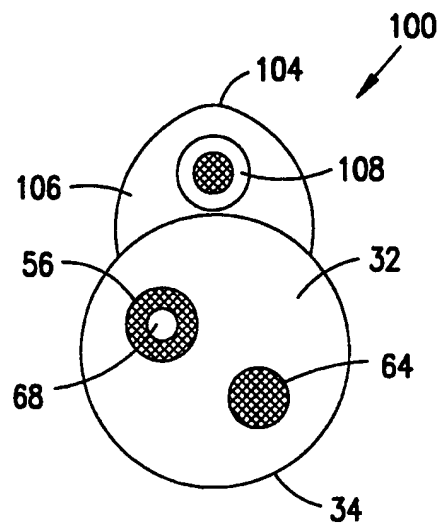


FIG. 6B

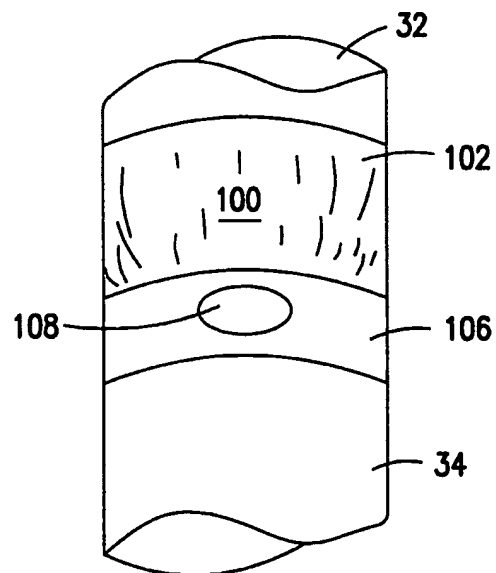


FIG. 6C

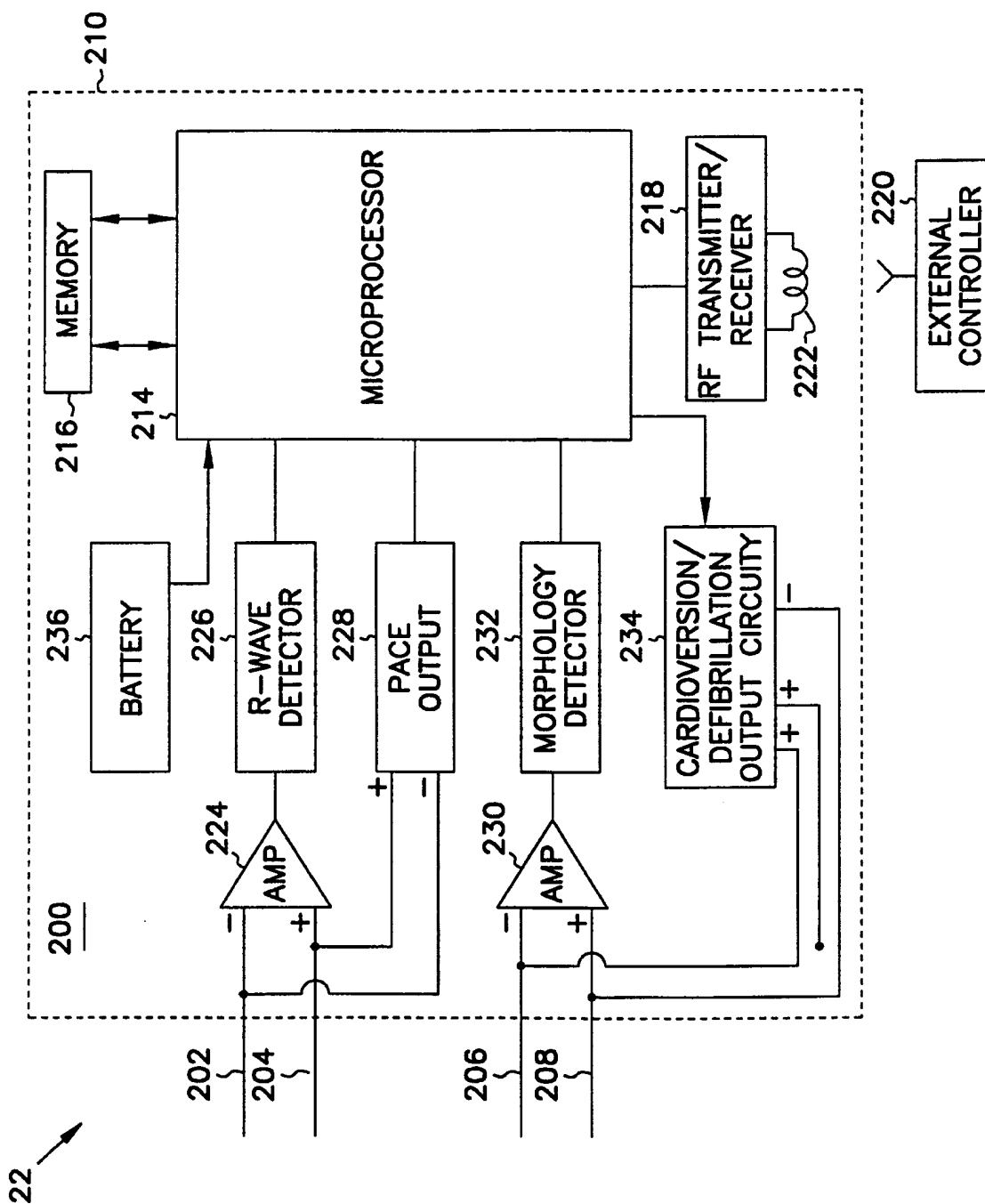


FIG. 7

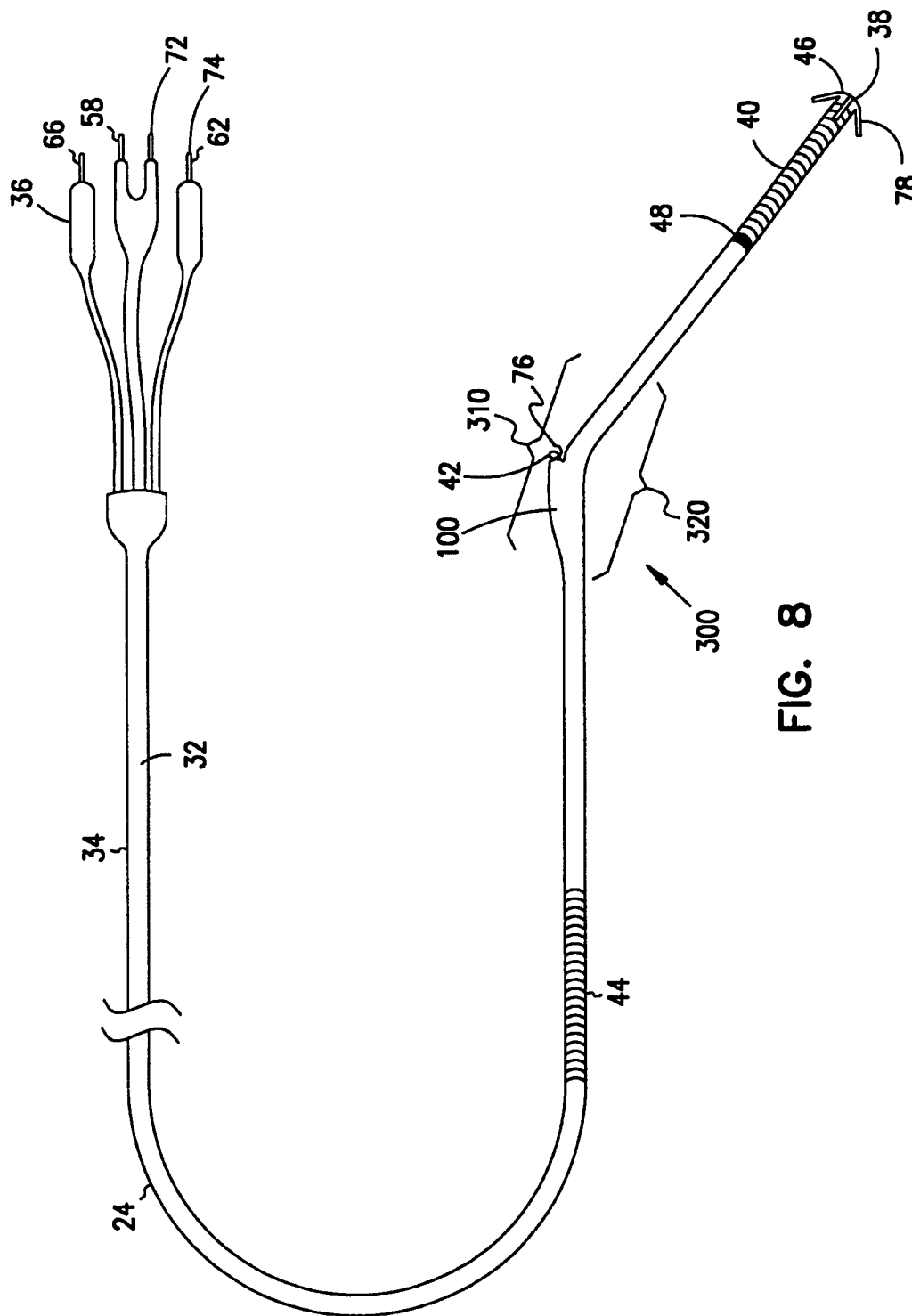


FIG. 8

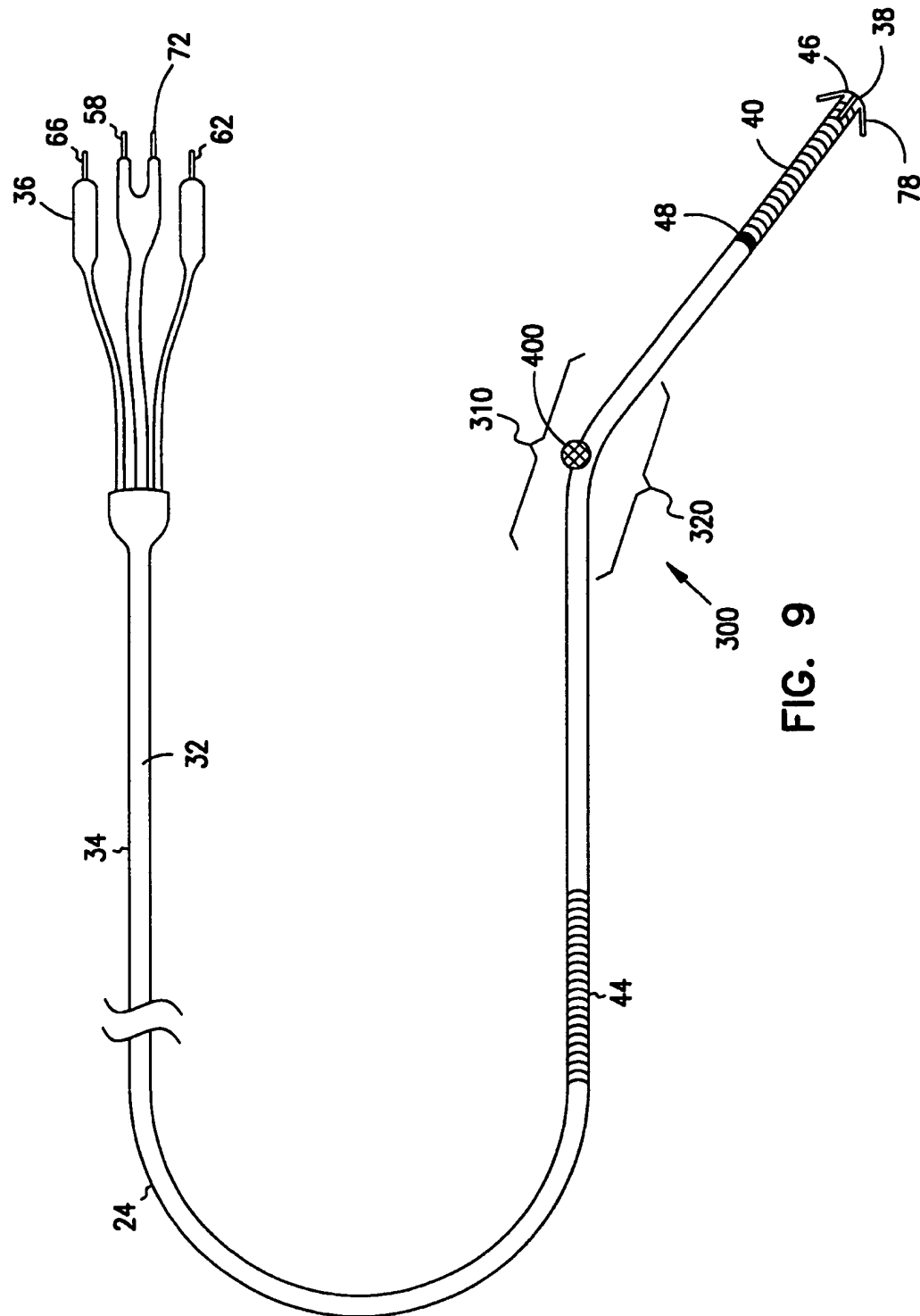
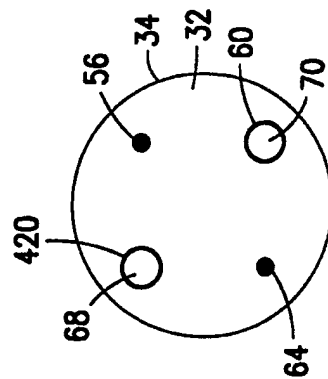
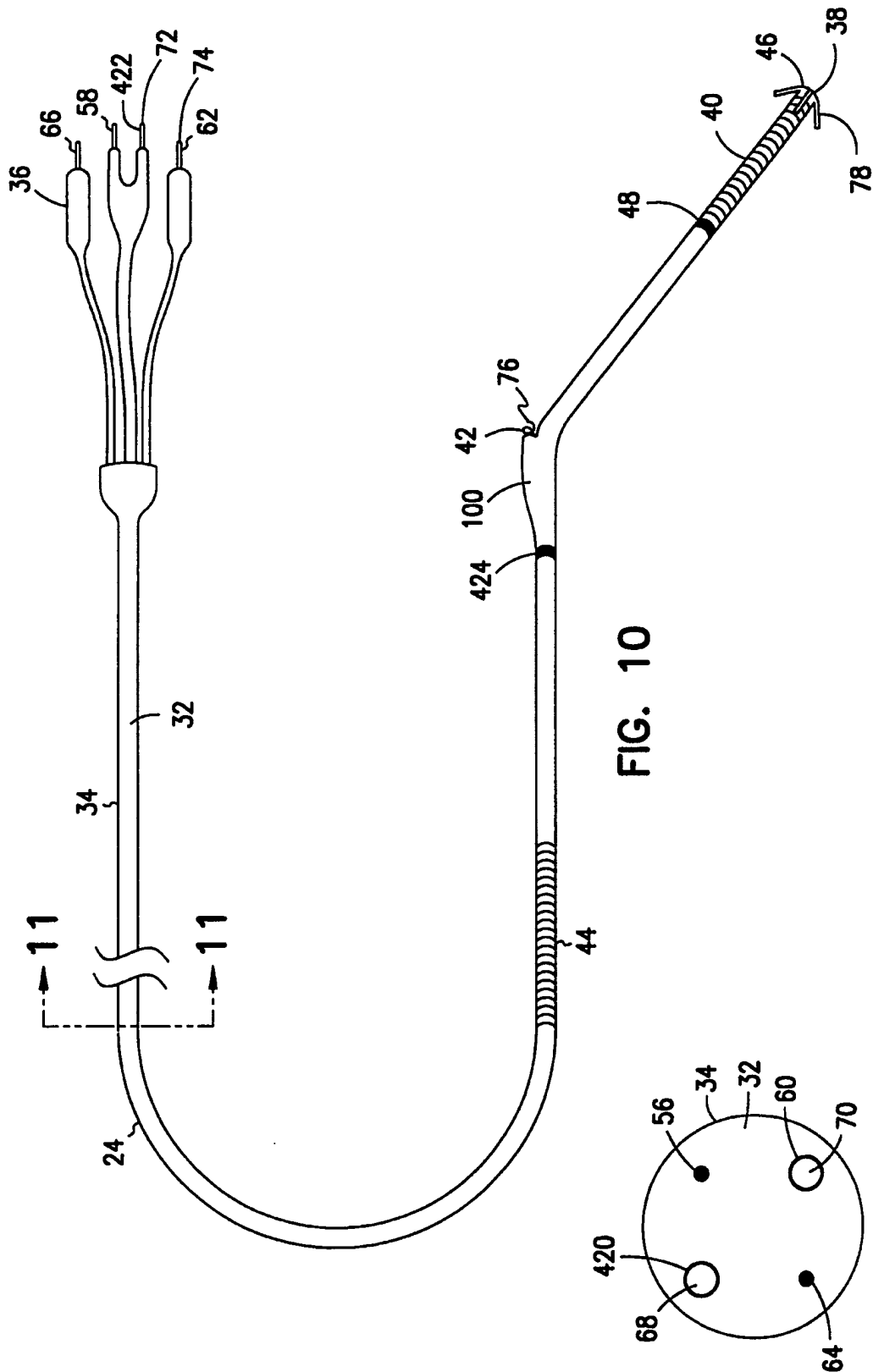


FIG. 9



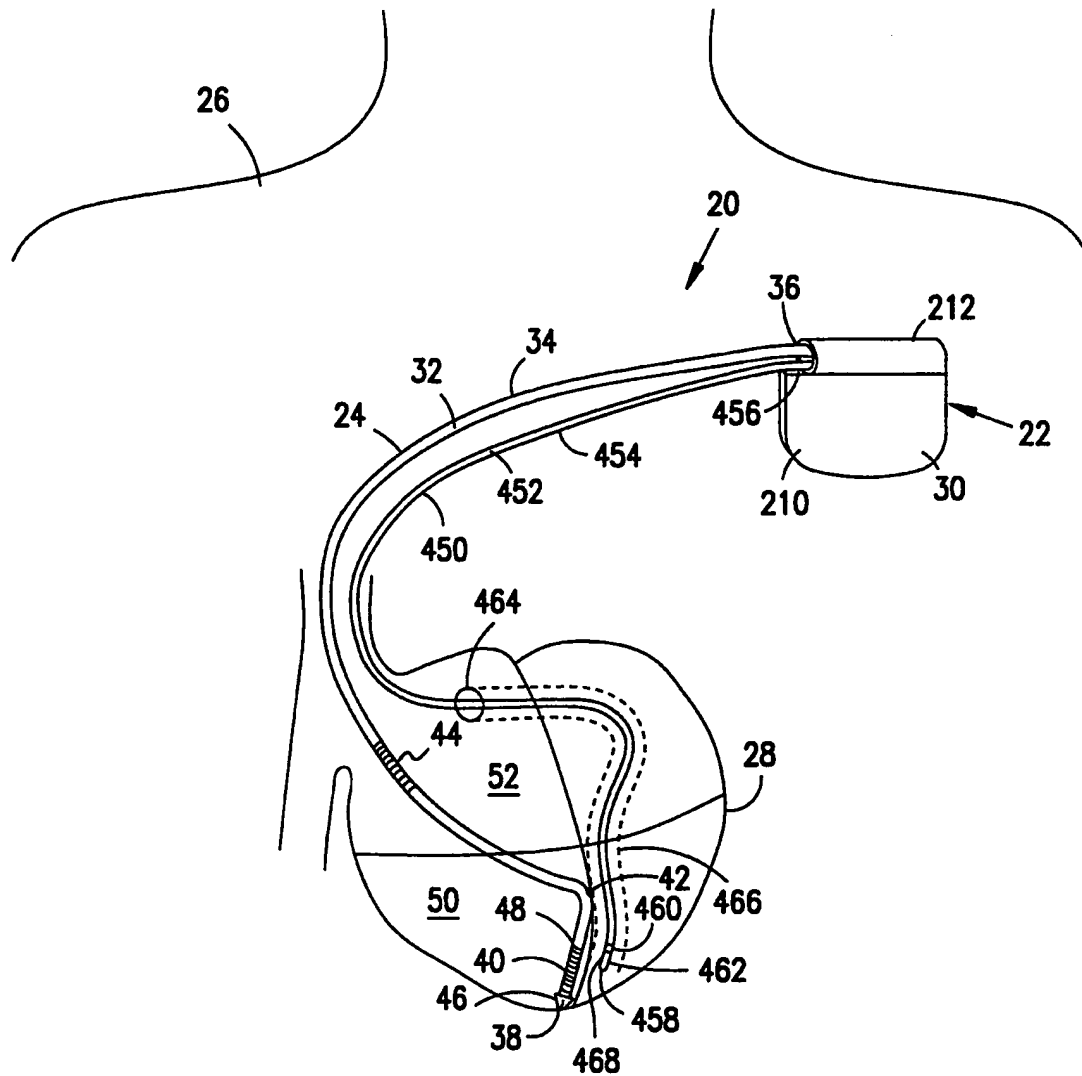


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/08344

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 08365 A (PACESETTER INC) 30 March 1995	1,3
A	see page 5, line 26 - page 8, line 13; figures 1-4	6,7,19
X	US 5 683 447 A (FAIN ERIC S ET AL) 4 November 1997	1,8
A	see column 3, line 63 - column 5, line 67; figures 1-4	3,6,7,9, 19
X	US 5 534 022 A (HOFFMANN DREW A ET AL) 9 July 1996	1,2,4-9, 13
A	see column 8, line 39 - column 9, line 20; figures 9-14	3,14,15, 19
	--- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

5 July 1999

Date of mailing of the international search report

12/07/1999

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INTERNATIONAL SEARCH REPORT

Interr 1st Application No

PCT/US 99/08344

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 813 886 A (BIOTRONIK MESS & THERAPIEG) 29 December 1997	1,5
A	see page 4, column 5, line 44 - page 5, column 8, line 42; figures 1-3 ---	6-9,18, 19
A	US 4 497 326 A (CURRY PAUL V L) 5 February 1985 see column 2, line 55 - column 3, line 57; figures 1-3 -----	7,8, 10-12,20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/08344

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9508365 A	30-03-1995	US 5466254 A AU 7799094 A EP 0670743 A JP 8503646 T	14-11-1995 10-04-1995 13-09-1995 23-04-1996
US 5683447 A	04-11-1997	NONE	
US 5534022 A	09-07-1996	NONE	
EP 0813886 A	29-12-1997	DE 19626352 A	02-01-1998
US 4497326 A	05-02-1985	EP 0062537 A	13-10-1982

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